

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :
Hiroyuki TOKUNAGA et al. : Attn: BOX PCT
Serial No. NEW : Docket No. 2001-1339A
Filed September 25, 2001 :

MEASURING APPARATUS USING
BIOSENSOR, BIOSENSOR USED
THEREFOR, AND EXCLUSIVE
STANDARD SOLUTION
[Corresponding to PCT/JP01/00471
Filed January 25, 2001]

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents,
Washington, DC 20231

Sir:

Prior to examination of the above-referenced U.S. patent application please amend the application as follows:

IN THE SPECIFICATION

Please amend the specification as follows:

Please replace the paragraph beginning at page 12, line 16, to page 13, line 1, with the following rewritten paragraph:

On the other hand, in contrast with the sensor, as a measuring device, one which is shown in figure 2 is employed. When a sensor 13 is mounted, the power to a measuring device 14 is turned on, and the measuring device is in a stand-by condition where a voltage of 0.5V is applied between the working electrode 1 and the third electrode 3 or between the counter 2 and the third electrode 3. This applied voltage values are different in accordance with the materials of the third electrode 3.

Please replace the paragraph beginning at page 18, line 22, to page 19, line 6, with the following rewritten paragraph:

The present invention provides a measuring apparatus which can automatically judge types of sample solution without artificial preoperation, a sensor used therefor, and an exclusive standard solution, comprises a third electrode besides a working electrode and a counter electrode, and judges types of sample solution by utilizing the fact that an oxidation current value obtained from the third electrode when the exclusive standard solution is a sample is significantly different from the oxidation current value obtained from the third electrode when blood is a sample.

200
201
202
203
204
205
206
207
208
209
210
211
212
213
214
215
216
217
218
219
220
221
222
223
224
225
226
227
228
229
230
231
232
233
234
235
236
237
238
239
240
241
242
243
244
245
246
247
248
249
250
251
252
253
254
255
256
257
258
259
260
261
262
263
264
265
266
267
268
269
270
271
272
273
274
275
276
277
278
279
280
281
282
283
284
285
286
287
288
289
290
291
292
293
294
295
296
297
298
299
300
301
302
303
304
305
306
307
308
309
310
311
312
313
314
315
316
317
318
319
320
321
322
323
324
325
326
327
328
329
330
331
332
333
334
335
336
337
338
339
340
341
342
343
344
345
346
347
348
349
350
351
352
353
354
355
356
357
358
359
360
361
362
363
364
365
366
367
368
369
370
371
372
373
374
375
376
377
378
379
380
381
382
383
384
385
386
387
388
389
390
391
392
393
394
395
396
397
398
399
400
401
402
403
404
405
406
407
408
409
410
411
412
413
414
415
416
417
418
419
420
421
422
423
424
425
426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447
448
449
450
451
452
453
454
455
456
457
458
459
460
461
462
463
464
465
466
467
468
469
470
471
472
473
474
475
476
477
478
479
480
481
482
483
484
485
486
487
488
489
490
491
492
493
494
495
496
497
498
499
500
501
502
503
504
505
506
507
508
509
510
511
512
513
514
515
516
517
518
519
520
521
522
523
524
525
526
527
528
529
530
531
532
533
534
535
536
537
538
539
540
541
542
543
544
545
546
547
548
549
550
551
552
553
554
555
556
557
558
559
560
561
562
563
564
565
566
567
568
569
570
571
572
573
574
575
576
577
578
579
580
581
582
583
584
585
586
587
588
589
590
591
592
593
594
595
596
597
598
599
600
601
602
603
604
605
606
607
608
609
610
611
612
613
614
615
616
617
618
619
620
621
622
623
624
625
626
627
628
629
630
631
632
633
634
635
636
637
638
639
640
641
642
643
644
645
646
647
648
649
650
651
652
653
654
655
656
657
658
659
660
661
662
663
664
665
666
667
668
669
670
671
672
673
674
675
676
677
678
679
680
681
682
683
684
685
686
687
688
689
690
691
692
693
694
695
696
697
698
699
700
701
702
703
704
705
706
707
708
709
710
711
712
713
714
715
716
717
718
719
720
721
722
723
724
725
726
727
728
729
730
731
732
733
734
735
736
737
738
739
740
741
742
743
744
745
746
747
748
749
750
751
752
753
754
755
756
757
758
759
760
761
762
763
764
765
766
767
768
769
770
771
772
773
774
775
776
777
778
779
780
781
782
783
784
785
786
787
788
789
790
791
792
793
794
795
796
797
798
799
800
801
802
803
804
805
806
807
808
809
810
811
812
813
814
815
816
817
818
819
820
821
822
823
824
825
826
827
828
829
830
831
832
833
834
835
836
837
838
839
840
841
842
843
844
845
846
847
848
849
850
851
852
853
854
855
856
857
858
859
860
861
862
863
864
865
866
867
868
869
870
871
872
873
874
875
876
877
878
879
880
881
882
883
884
885
886
887
888
889
890
891
892
893
894
895
896
897
898
899
900
901
902
903
904
905
906
907
908
909
910
911
912
913
914
915
916
917
918
919
920
921
922
923
924
925
926
927
928
929
930
931
932
933
934
935
936
937
938
939
940
941
942
943
944
945
946
947
948
949
950
951
952
953
954
955
956
957
958
959
960
961
962
963
964
965
966
967
968
969
970
971
972
973
974
975
976
977
978
979
980
981
982
983
984
985
986
987
988
989
990
991
992
993
994
995
996
997
998
999
1000

REMARKS

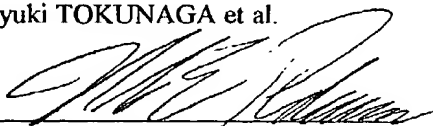
The above amendments have been made to make minor editorial changes so as to generally improve the form of the specification.

Attached hereto is a marked-up version of the changes made to the specification by the current Preliminary Amendment. The attached page is captioned "**Version With Markings to Show Changes Made**".

Respectfully submitted,

Hiroyuki TOKUNAGA et al.

By



Nils E. Pedersen
Registration No. 33,145
Attorney for Applicants

NEP/krl
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
September 25, 2001

THE COMMISSIONER IS AUTHORIZED
TO DEPOSIT IN OFFICE IN THE
FEE FOR THIS PAPER TO DEPOSIT
ACCOUNT NO. 23-0975

3 is arranged in a position where the third electrode 3 comes in contact with the measurement sample, it may be arranged in any position.

Further, the third electrode 3 consists of easily oxidized materials as compared with the working electrode 1 and the counter electrode 2, and, for example, silver, copper, zinc, or mixed materials including them correspond to the easily oxidized materials. In this embodiment, a silver electrode is employed as the third electrode 3.

When the sensor so constructed comes in contact with the opening 9 of the sample supplying groove 10, a fixed quantity (here, as approximately $3\mu\text{L}$) of the sample is introduced into the reaction layer 12 and the respective electrode parts 1, 2 and 3 by capillary action, whereby suction of the samples reaches the third electrode 3 and then stops.

16 On the other hand, in contrast with the sensor, as a measuring device, one which is shown in figure 2 is employed. When a sensor 13 is mounted, the power to a measuring device 14 is turned on, and the measuring device is in a stand-by condition where a voltage of 0.5V is applied between the working electrode 1 and the third electrode 3 or between the counter 2 and the third electrode 3. This [applied voltage is a voltage which is lower than that of dissolution potential of materials used for the third electrode 3, and] applied voltage values [thereof] are different in accordance with the materials of the

third electrode 3.

When a sample is introduced into the sensor 13 during the stand-by condition of the measuring device 14, a fixed quantity (here, as approximately $3\mu\text{L}$) of the sample is introduced into the reaction layer 12 and the respective electrode parts by capillary action via the sample supplying groove 10. Thereafter, when oxidation current which is measured in the third electrode 3 is the fixed quantity (here, as $0.3\mu\text{A}/0.5$ second) or more, an application of the voltage to the sensor 13 is once stopped, and the reaction proceeds for a predetermined time.

After the predetermined time has elapsed, the voltage is applied again, and the current value corresponding to glucose level is measured. The measurement of the current value corresponding to this glucose level is made, specifically, by applying a voltage of 0.5V between the working electrode 1 and the counter electrode 2 or among the working electrode 1, the counter electrode 2, and the third electrode 3, and measuring the current value obtained in the working electrode 1 at that time.

Next, the exclusive standard solution used for the measuring device 14 using the glucose sensor according to the present invention will be described.

The exclusive standard solution is characterized by further merging a substance which suppresses oxidation current

automatically judging whether the type of sample solution is the standard solution sample or the blood sample. Further, if the foregoing is previously programmed in the measuring device 14, when the current value corresponding to glucose level after applying the voltage again is displayed and stored, the whole blood sample and the standard solution sample can be full-automatically discriminated between to be displayed and stored.

Further, while the glucose sensor is taken as an example in this embodiment, the similar effect can be obtained as long as a measuring device for a simple type electrode biosensor, a sensor, and a standard solution are used for cholesterol, lactic acid or the like.

In addition, while one in which the judgment of the types of sample solution is made by comparing the oxidation current value obtained from the third electrode 3 to the predetermined threshold value is described in this embodiment, the judgment of the types of sample solution may be made on the basis of a difference between the time variations of the oxidation current values obtained from the third electrode 3.

Industrial Availability

22 The present invention provides a measuring apparatus which can automatically judge types of sample solution without artificial preoperation, a sensor used therefor, and an exclusive standard solution, comprises a third electrode
